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10/529,413	06/23/2005	Daniel Christopher Brookings	07-993-WO-US	6765

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MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP

300 S. WACKER DRIVE

32ND FLOOR

CHICAGO, IL 60606

EXAMINER

MABRY, JOHN

ART UNIT

PAPER NUMBER

1625

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/529,413

**Applicant(s)**

BROOKINGS ET AL.

**Examiner**

John Mabry, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 7-9 is/are pending in the application.
- 4a) Of the above claim(s) 12-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 7-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Examiner's Response***

Applicant's response on October 22, 2007 filed in response to the Election/Restriction dated September 21, 2007 has been received and duly noted. The Examiner acknowledges Applicants' election of Group VI without traverse.

Thus, the restriction requirement is deemed proper and **FINAL**.

Applicant's response on February 15, 2008 filed in response to the Office Action dated November 15, 2008 has been received and duly noted.

In view of this response, the status of the rejections/objections of record is as follows:

***Status of the Claims***

Claims 1 and 7-9 are pending and rejected.

Claims 2-6 and 10-11 have been cancelled.

Claims 12-21 directed towards non-elected subject matter.

***35 USC § 112 Rejection(s)***

The 112-2<sup>nd</sup> rejection of claims 1-9 regarding the phrase "a linker atom or group" have been overcome in view of Applicants amendment to the claim - deleting the phrase "a linker atom or group".

The 112-1<sup>st</sup> rejection of claims 1-9 regarding the terms "solvate and hydrate" have not been overcome in view of Applicants amendment – these terms remain present in claim 9.

The 112-1<sup>st</sup> rejection of claims 1-9 regarding the scope of enablement for "R1 and R2" have not been overcome in view of Applicants amending the claims. R1 and R2 have been deleted and currently have no antecedent basis. The rejection in view of Applicant's amendment is below.

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The 112-1<sup>st</sup> rejection of claims 1-9 regarding the scope of enablement for "(Alk1)<sub>n</sub>L1Cy1" have not been overcome in view of Applicants amending the claims. As described in previous Non-Final Office Action, Alk1 is not enabled to be "substituted aliphatic or heteroaliphatic chain". The definition of the term "substituted" as defined in the Specification (page 7, lines 17-30) is as follows:

Optional substituents which may be present on any of these alkyl, alkenyl or alkynyl groups include one, two, three or more substituents where each substituent may be the same or different and is selected from a halogen atom and an -OH, -CO<sub>2</sub>H, -CO<sub>2</sub>R<sup>4</sup> (where R<sup>4</sup> is an optionally substituted straight or branched C<sub>1-6</sub> alkyl group), -CONH<sub>2</sub>, -CONHR<sup>4</sup>, -CON(R<sup>4</sup>)<sub>2</sub>, -COR<sup>4</sup>, C<sub>1-6</sub> alkoxy, halo(C<sub>1-6</sub>alkoxy), -S(O)R<sup>4</sup>, -S(O)<sub>2</sub>R<sup>4</sup>, C<sub>1-6</sub> alkylthio, -NH<sub>2</sub>, -NHR<sup>4</sup>, -N(R<sup>4</sup>)<sub>2</sub>, -S(O)<sub>2</sub>NH<sub>2</sub>, -S(O)<sub>2</sub>NHR<sup>4</sup>, -S(O)<sub>2</sub>N(R<sup>4</sup>)<sub>2</sub>, -NHC(O)R<sup>4</sup>, -N(R<sup>4</sup>)C(O)R<sup>4</sup>, -NHS(O)<sub>2</sub>R<sup>4</sup>, -N(R<sup>4</sup>)S(O)<sub>2</sub>R<sup>4</sup>, -NHS(O)<sub>2</sub>NH<sub>2</sub>, -NHS(O)<sub>2</sub>NHR<sup>4</sup>, -NHS(O)<sub>2</sub>N(R<sup>4</sup>)<sub>2</sub>, -N(R<sup>4</sup>)S(O)<sub>2</sub>NH<sub>2</sub>, -N(R<sup>4</sup>)S(O)<sub>2</sub>NHR<sup>4</sup> or -N(R<sup>4</sup>)S(O)<sub>2</sub>N(R<sup>4</sup>)<sub>2</sub> group. Where two R<sup>4</sup> groups are present in a group, these may be the same or different or may be joined, together with the N atom to which they are attached, to form a heterocyclic ring. Such heterocyclic rings may be optionally interrupted by a further heteroatom or heteroatom-containing group selected from -O-, -S-, -NH-, -N(R<sup>4</sup>)-, -C(O)- and -C(S)- groups. Particular examples of such heterocyclic rings include piperidinyl, pyrazolidinyl, morpholinyl, thiomorpholinyl, pyrrolidinyl, imidazolidinyl or piperazinyl rings.

The variable Alk1 is not enablement for any of these optional substituents.

Moreover, Applicant is not enabled for Alk1, in part, because Applicant shows no working examples and does not provide any guidance for the existence of Alk1.

Furthermore, Applicant has amended claims where (Alk1)<sub>n</sub> wherein n only equal zero. An appropriate action is requested to overcome this rejection.

***35 USC § 103(a) Rejection(s)***

Applicant's arguments with respect to 103(a) rejections have been fully considered and are persuasive. The 103(a) rejection of claims 1-9 regarding obviousness over US 7,176,215 and US 2006/0025428 have been withdrawn.

***Obviousness-Type Double Patenting Rejection(s)***

The obviousness-type double patenting rejected has not been overcome over US 7,176,215 and US 2006/0025428. A properly executed Terminal Disclaimer is required to overcome rejection.

An action on the merits of claims 1 and 7-9 is contained herein below.

**DETAILED ACTION**

Applicant is respectfully reminded that it is required that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "R1 and R2". However, the substituents from which they are a part of have been deleted (see corresponding section of claim 1 below). There is insufficient antecedent basis for this limitation in the claim.

~~R<sup>a</sup> and R<sup>b</sup> are each hydrogen; R<sup>a</sup>, R<sup>b</sup> and R<sup>c</sup> are each independently a hydrogen or halogen atom or an optionally substituted alkyl, -CN, -CO<sub>2</sub>R<sup>1</sup> or -CONR<sup>1</sup>R<sup>2</sup> group.~~

~~R<sup>1</sup> and R<sup>2</sup> are each, independently, a hydrogen atom or an optionally substituted alkyl group.~~

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

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the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Conclusion***

Applicant is respectfully reminded that it is required that all claims be amended to elected group. Examiner also warns Applicant not to introduce new matter when amending.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, PhD, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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/John Mabry, PhD/

Examiner

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/Rita J. Desai/

Primary Examiner, Art Unit 1625